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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,123	02/10/2005	Jose Ignacio Andres-Gil	JAB1747USPCT	4854

27777 7590 05/17/2007

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EXAMINER	
LEESER, ERICH A	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
05/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,123	ANDRES-GIL ET AL.	
	Examiner	Art Unit	
	Erich A. Leeser	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 2-10-05.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10,12 and 13 is/are pending in the application.

4a) Of the above claim(s) 7 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-6,8-10,12 and 13 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Claim 7 is a non-statutory "use" claim, which is withdrawn from consideration. Cancellation is recommended.

I. Claims 1-6, 8-10 and 13, drawn to chemical compounds according to Formula (I), wherein Het is pyridinyl, pharmaceutical compositions comprising such compounds and a process for making such pharmaceutical compositions.

II. Claims 1-6, 8-10 and 13, drawn to chemical compounds according to Formula (I), wherein Het is pyrazinyl, pharmaceutical compositions comprising such compounds and a process for making such pharmaceutical compositions.

III. Claims 1-6, 8-10 and 13, drawn to chemical compounds according to Formula (I), wherein Het is pyrimidinyl, pharmaceutical compositions comprising such compounds and a process for making such pharmaceutical compositions.

IV. Claims 1-6, 8-10 and 13, drawn to chemical compounds according to Formula (I), wherein Het is pyridazinyl, pharmaceutical compositions comprising such compounds and a process for making such pharmaceutical compositions.

V. Claims 1-6, 8-10 and 13, drawn to chemical compounds according to Formula (I), wherein Het is furanyl, pharmaceutical compositions comprising such compounds and a process for making such pharmaceutical compositions.

VI. Claims 1-6, 8-10 and 13, drawn to chemical compounds according to Formula (I), wherein Het is thienyl, pharmaceutical compositions comprising such compounds and a process for making such pharmaceutical compositions.

VII. Claims 1-6, 8-10 and 13, drawn to chemical compounds according to Formula (I), wherein Het is pyrrolyl, pharmaceutical compositions comprising such compounds and a process for making such pharmaceutical compositions.

VIII. Claims 1-6, 8-10 and 13, drawn to chemical compounds according to Formula (I), wherein Het is oxazolyl, pharmaceutical compositions comprising such compounds and a process for making such pharmaceutical compositions.

IX. Claims 1-6, 8-10 and 13, drawn to chemical compounds according to Formula (I), wherein Het is thiazolyl, pharmaceutical compositions comprising such compounds and a process for making such pharmaceutical compositions.

X. Claims 1-6, 8-10 and 13, drawn to chemical compounds according to Formula (I), wherein Het is imidazolyl, pharmaceutical compositions comprising such compounds and a process for making such pharmaceutical compositions.

XI. Claims 1-6, 8-10 and 13, drawn to chemical compounds according to Formula (I), wherein Het is pyrazolyl, pharmaceutical compositions comprising such compounds and a process for making such pharmaceutical compositions.

XII. Claims 1-6, 8-10 and 13, drawn to chemical compounds according to Formula (I), wherein Het is isothiazolyl, pharmaceutical compositions comprising such compounds and a process for making such pharmaceutical compositions.

XIII. Claims 1-6, 8-10 and 13, drawn to chemical compounds according to Formula (I), wherein Het is isoxazolyl, pharmaceutical compositions comprising such compounds and a process for making such pharmaceutical compositions.

XIV. Claims 1-6, 8-10 and 13, drawn to chemical compounds according to Formula (I), wherein Het is oxadiazolyl, pharmaceutical compositions comprising such compounds and a process for making such pharmaceutical compositions.

XV. Claims 1-6, 8-10 and 13, drawn to chemical compounds according to Formula (I), wherein Het is triazolyl, pharmaceutical compositions comprising such compounds and a process for making such pharmaceutical compositions.

XVI. Claim 12, drawn to a method for the manufacture of a medicament for the treatment and/or prophylaxis of the various types of disorders which are recited in the claim, wherein the medicament is employed for the treatment of said disorders, said treatment comprising administering a therapeutic amount of a compound according to Group I.

XVII. Claim 12, drawn to a method for the manufacture of a medicament for the treatment and/or prophylaxis of the various types of disorders which are recited in the claim, wherein the

medicament is employed for the treatment of said disorders, said treatment comprising administering a therapeutic amount of a compound according to Group II.

XVIII. Claim 12, drawn to a method for the manufacture of a medicament for the treatment and/or prophylaxis of the various types of disorders which are recited in the claim, wherein the medicament is employed for the treatment of said disorders, said treatment comprising administering a therapeutic amount of a compound according to Group III.

XIX. Claim 12, drawn to a method for the manufacture of a medicament for the treatment and/or prophylaxis of the various types of disorders which are recited in the claim, wherein the medicament is employed for the treatment of said disorders, said treatment comprising administering a therapeutic amount of a compound according to Group IV.

XX. Claim 12, drawn to a method for the manufacture of a medicament for the treatment and/or prophylaxis of the various types of disorders which are recited in the claim, wherein the medicament is employed for the treatment of said disorders, said treatment comprising administering a therapeutic amount of a compound according to Group V.

XXI. Claim 12, drawn to a method for the manufacture of a medicament for the treatment and/or prophylaxis of the various types of disorders which are recited in the claim, wherein the medicament is employed for the treatment of said disorders, said treatment comprising administering a therapeutic amount of a compound according to Group VI.

XXII. Claim 12, drawn to a method for the manufacture of a medicament for the treatment and/or prophylaxis of the various types of disorders which are recited in the claim, wherein the medicament is employed for the treatment of said disorders, said treatment comprising administering a therapeutic amount of a compound according to Group VII.

XXIII. Claim 12, drawn to a method for the manufacture of a medicament for the treatment and/or prophylaxis of the various types of disorders which are recited in the claim, wherein the medicament is employed for the treatment of said disorders, said treatment comprising administering a therapeutic amount of a compound according to Group VIII.

XXIV. Claim 12, drawn to a method for the manufacture of a medicament for the treatment and/or prophylaxis of the various types of disorders which are recited in the claim, wherein the medicament is employed for the treatment of said disorders, said treatment comprising administering a therapeutic amount of a compound according to Group IX.

XXV. Claim 12, drawn to a method for the manufacture of a medicament for the treatment and/or prophylaxis of the various types of disorders which are recited in the claim, wherein the medicament is employed for the treatment of said disorders, said treatment comprising administering a therapeutic amount of a compound according to Group X.

XXVI. Claim 12, drawn to a method for the manufacture of a medicament for the treatment and/or prophylaxis of the various types of disorders which are recited in the claim, wherein the medicament is employed for the treatment of said disorders, said treatment comprising administering a therapeutic amount of a compound according to Group XI.

XXVII. Claim 12, drawn to a method for the manufacture of a medicament for the treatment and/or prophylaxis of the various types of disorders which are recited in the claim, wherein the medicament is employed for the treatment of said disorders, said treatment comprising administering a therapeutic amount of a compound according to Group XII.

XXVIII. Claim 12, drawn to a method for the manufacture of a medicament for the treatment and/or prophylaxis of the various types of disorders which are recited in the claim, wherein the medicament is employed for the treatment of said disorders, said treatment comprising administering a therapeutic amount of a compound according to Group XIII.

XXIX. Claim 12, drawn to a method for the manufacture of a medicament for the treatment and/or prophylaxis of the various types of disorders which are recited in the claim, wherein the medicament is employed for the treatment of said disorders, said treatment comprising administering a therapeutic amount of a compound according to Group XIV.

XXX. Claim 12, drawn to a method for the manufacture of a medicament for the treatment and/or prophylaxis of the various types of disorders which are recited in the claim, wherein the medicament is employed for the treatment of said disorders, said treatment comprising administering a therapeutic amount of a compound according to Group XV.

The examiner has required restriction between compounds, pharmaceutical compositions, and a claim drawn to a method for the manufacture of a medicament for the treatment and/or prophylaxis of various diseases ("claim 12"). Where applicant elects claims directed to compounds, and a compound claim is subsequently found allowable, withdrawn claim 12, insofar as it depends from or otherwise includes all the limitations of the allowable compound claim will be rejoined in accordance with the provisions of MPEP § 821.04.

In the event of rejoinder, the requirement for restriction between the compound claims and rejoined claim 12 will be withdrawn, and rejoined claim 12 will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.

Until an elected compound claim is found allowable, an otherwise proper restriction requirement between compound claims and claim 12 may be maintained. Withdrawn claims that are not commensurate in scope with an allowed compound claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light *of In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The inventions listed as Groups I to XXX do not relate to a single general inventive concept under 35 USC 121 or PCT Rule 13.1 because:

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

PCT Rule 13.2 states that the unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, **Part 1(a)**, indicates that the application should relate to only one invention, of if there is more than one invention, inclusion is permitted if they are so linked to form a single general inventive concept.

Annex B **Part 1(b)**, indicates that "special technical features" means those features that as a whole define a contribution over the prior art.

Annex B **Part 1(c)**, further defines independent and dependent claims. Unity of invention only is concerned in relation to independent claims. Dependent claims are defined as a claim that contains all the features of another claim and is in the same category as the other claim. The category of a claim refers to the classification of claims according to subject matter e.g. product, process, use, apparatus, means, etc.

Annex B **Part 1(e)**, indicates that the permissible combinations of different categories of claims. **Part 1(e)I**, states that inclusion of an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product is permissible.

Annex B**, Part 1(f)**, indicates the "Markush practice" of alternatives in a single claim. **Part 1(f)I**, indicates the technical relationship and the same or corresponding special technical feature is considered to be met when (A) all alternatives have a common property or activity, and (B) a common structure is present or al alternatives belong to a recognized class of chemical compounds. Further defining (B), Annex B, **Part 1(f)(I-iii)**, the common structure must; a) occupy a large portion of their structure, or b) the common structure constitutes a structurally distinctive portion, or c) where the structures are equivalent and therefore a recognized class of chemical compounds, each member could be substituted for one another with the same intended result. That is, with a common or equivalent structure, there is an expectation relationship and the corresponding special technical feature result from a common (or equivalent) structure that is responsible for the common activity (or property). **Part 1(f) iv**, indicates that when all alternatives of a Markush grouping can be differently classified, it shall no, take alone, be considered justification for finding a lack of unity. **Part 1(f)v**, indicates that "When dealing with

alternatives, if it can be shown that at least *one* Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner."

In the instant case, at least one Markush alternative is not novel because compound 3,3a,4,5,8,9-hexahydro-3-[[4-[(2E)-3-phenyl-2-propenyl]-1-piperazinyl]methyl]-furo[2',3':6,7]naphth[1,2-c]isoxazole found in prior art by Andres-Gil, et al., WO 02/066484 anticipates the present invention, thus the lacking of unity of invention has been found.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call was made to Applicant's counsel on April 23, 2007 to request an oral election to the above restriction requirement, but did not result in an election being made.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Erich A. Leeser whose telephone number is 571-272-9932. The Examiner can normally be reached Monday through Friday from 8:30 to 6:00 EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) toll-free at 866-217-9197. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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